

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 31, 2003 (68 FR 62088). The amendment is being made to reflect a change in the *Contact Person* for the FDA advisory committee telephone line extension codes (namely from 5-digit to a 10-digit format), *Agenda*, and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Anuja Patel, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776 or e-mail: patela@cder.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 31, 2003 (68 FR 62088), FDA announced that a meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee will be held on February 2, 2004. On page 62088,

in the second and third columns, the *Contact Person*, *Agenda*, and *Procedure* portions of the meeting are amended to read as follows:

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776 or e-mail: *patela@cder.fda.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 3014512544. Please call the Information Line for up to date information on this meeting.

Agenda: The Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee will discuss reports of the occurrence of suicidality (both suicidal ideation and suicide attempts) in clinical trials for various anti-depressant drugs in pediatric patients with major depressive disorder (MDD). The committee will consider optimal approaches to the analysis of data from these trials as well as further research needs to address these issues. The committee will not be considering options for definitive regulatory action at this meeting because definitive analyses of the data have not been completed. This topic will be covered in a second meeting to be scheduled by summer 2004.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 26, 2004. Oral presentations from the public will be scheduled between approximately 9:30 a.m. to 11:30 a.m., and 2 p.m. to 2:30 p.m.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 5, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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